

REMARKS

Claims 1-20 are pending in the present application and have been rejected. Claims 1, 10, 11 and 19 have been amended herein. Reconsideration and withdrawal of the rejections are respectfully requested in light of the above amendments and the following remarks.

The Examiner has required correction of the Abstract. The Abstract has been amended herein to meet all of the requirements. As such, it is respectfully submitted that the Abstract is acceptable.

The Examiner has also advised applicant of its obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made. Application submits that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made.

Claims 1-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over McWha et al (U.S. Patent No. 5,480,389) in view of Shaffer (U.S. Patent No. 5,429,616). The Examiner has stated that McWha discloses a spinal epidural needle comprising an elongate tube with a sharpened distal end, an attached hub, a spinal needle and indicia for location. The Examiner then relies on Shaffer for disclosing a resilient member permanently mounted with a hub and a deformable U-shaped clamp with living hinge with and a releasable latch push tab and support arms oriented for perpendicular movement to the elongate tube. The Examiner further states that Shaffer discloses that the resilient member defines a radiused portion and the pair of legs defines a radiused portion substantially the same as the radiused portion of the resilient member.

Shaffer discloses “an occludable catheter apparatus. . .which blocks the escape of blood when the insertion needle assembly 12, including a needle 14 and a needle hub 16, is removed.” (Col. 4, lns. 21-24). Locking member 44 and 46 are gripped by the medical provider immediately after the needle 14 is withdrawn from the catheter 40 and catheter hub 34 and sealing material 50 *closes the catheter hub 24 completely*. (Col. 5, lns. 12-16). Thus the clamp disclosed in Shaffer occludes the catheter to prevent the escape of blood.

The present invention, as recited in the amended claims, includes a clamp that is selectively moveable between an open position and a clamp position. The clamp position is illustrated in Figs. 5B and 10, which shows the reduction of the inner diameter of opening 34. In the clamp position, the epidural needle is fixed relative to the spinal needle. As illustrated, however, in the clamp position, the spinal needle is not occluded. Thus, the clamp serves to fix the position of the spinal needle 14 relative to the epidural needle 14. (See Paragraph [0039]). If, in the clamp position, the spinal needle was occluded, the practitioner would be unable to deliver medication rapidly through the spinal needle to initiate and maintain a therapeutic level of medicament, which is one of the desirable advantages of the present invention.

Independent claims 1, 10 and 19 have been amended herein to recite that in the clamp position, the resilient member and/or the inner diameter of the tube is not occluded. This amendment is supported in the specification, in Figs. 5B and 10, as well as at paragraph [0038]. According to the specification, at paragraph [0038], once placement of the spinal needle 14 in the subarachnoid space 60 is achieved and confirmed, which occurs after the latch of the clamp is engaged, the practitioner can attach a fluid handling device and instill the medication through the spinal needle. Thus, it is believed that this amendment does not constitute new matter.

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. §2142 A *prima facie* case of obviousness has not been established here, since neither of the prior art reference teaches a clamp position which does not occlude the pathway, but merely fixes an introducer needle to the spinal needle. Therefore, it is respectfully submitted that the 35 U.S.C. §103 rejection must be withdrawn with respect to independent claims 1, 10 and 19. In addition, since the remaining claims depend, directly or indirectly from these independent claims, it is respectfully submitted that the 35 U.S.C. §103 rejection should be withdrawn with respect to these claims as well.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (201) 847-6797 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 02-1666 therefor.

Dated: March 2, 2007

Respectfully submitted,

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